UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 6, 2006

MEMORANDUM

Subject: Efficacy Review for Brace, EPA Reg. No. 777-99; DP Barcode: D332243

From: Ibrahim Laniyan, Microbiologist
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Thru: Tajah Blackburn, Acting Team Leader
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To: Stacey Gribsby / Adam Heyward
Regulatory Management Branch II
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Applicant: Reckitt Benckiser Inc.
Morris Corporate center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Formulation from the Label:

Active Ingredient	% by wt.
Akyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium saccharinate	0.10 %
Ethanol	58.00 %
Other Ingredients:	41.90 %
Total	100.00 %

I. BACKGROUND

The product, Brace (EPA Reg. No. 777-99), is an EPA-approved disinfectant (bactericide, fungicide, tuberculocide, virucide), non-food contact surface sanitizer, and fungistat for use on hard, non-porous surfaces in household, institutional, industrial, commercial, animal care, and hospital or medical environments. The product is an aerosol. The applicant requested to amend the registration of this product to add claims for effectiveness as a disinfectant and sanitizer against additional microorganisms. In addition, the applicant requested to amend the registration of this product to add claims for effectiveness on soft surfaces. Studies were conducted at Reckitt Benckiser Inc.'s Microbiology Laboratory, located at One Philips Parkway in Montvale, NJ 07645; ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121; and MicroBioTest, Inc., located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant to EPA (dated August 18, 2006), 30 studies (MRID Nos. 469185-01 through 469185-30), Statements of No Data Confidentiality Claims for all 30 studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, Formula 677-180. Information provided in a data package previously reviewed by EPA (i.e., D322210; dated December 7, 2005) indicates that the tested product, Formula 677-180, is the basic formula (Spring Waterfall Scent #1) of the product, Brace, which is the subject of this efficacy review report.

II. USE DIRECTIONS

The product is designed to be used for disinfecting and sanitizing hard, non-porous surfaces such as appliance exteriors, bathtubs, bed frames and bed springs, cabinets, cat litter boxes, carts, counter tops, cuspidors, furniture, diaper changing tables and pails, dish pails and racks, door knobs, drinking fountains, examination tables, faucets, fixtures, floors, garbage cans, lamps, laundry baskets, metal blinds, mirrors, outdoor furniture, recycling bins, remote controls, showers, sinks, sports equipment, stretchers, toilets, toys, telephones, tools, urinals, walls, wheelchairs, whirlpool interiors, and windows. The proposed label also indicated that the product can be used on surfaces such as ceramic tile, crystal, enamel, glass, glazed ceramic tile, glazed porcelain, laminate, linoleum, marble, Marlite, metal (e.g., brass, chrome, copper, stainless steel, tin), Parquet, plastic, Plexiglas, sealed granite, and vinyl. Directions on the proposed label provided the following information regarding use of the product:

> As a disinfectant: Pre-clean surfaces prior to use. Hold container upright 6-8 inches from surface. Spray for 2-3 seconds until covered with mist. Let stand for 10 minutes to air dry. Food contact surfaces must be thoroughly rinsed with potable water.
>
> As a sanitizer: Pre-clean surfaces prior to use. Hold container upright 6-8 inches from surface. Spray for 2-3 seconds until covered with mist. Let stand for 30 seconds, then rinse thoroughly.
>
> To control and prevent mold and mildew: Pre-clean surfaces. Spray surface and allow to remain wet for 10 minutes. Allow surface to air dry. Repeat applications in weekly intervals.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Germicidal Spray Products as Disinfectants Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Germicidal Spray Products as Disinfectants Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required. These Agency standards are presented in DIS/TSS-6.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. The Agency recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Sanitizers (For Non-Food Contact Surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-10 may be used. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 469185-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Vaccinia virus for Formula 677-180, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – August 3, 2005. Study Identification Number A03038.

This study was conducted against Vaccinia virus (Strain WR; ATCC VR-119) using Vero cells (ATCC CCL-81; propagated in-house) as the host system. Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to ATS Labs Protocol No. REK01062105.VAC (copy not provided). The product was received ready-to-use in aerosol spray cans. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were made by spreading 0.2 mL of stock virus on the bottoms of separate sterile, glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 48% relative humidity. For each product lot, one dried virus film was sprayed for 3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 30 seconds at 20.0°C. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The subcultures were incubated at 37.0°C in a humidified atmosphere of 5.9-6.1% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus titer, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The average titer of the dried virus control was **7.75 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the average reduction in viral titer was **≥7.25 $\log_{10}$** for both batches.

2. MRID 469185-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Cytomegalovirus (ATCC VR-538) for Formula 677-

180, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – October 27, 2005. Project Number A03037.

This study was conducted against Cytomegalovirus (Strain AD-169; ATCC VR-538) using MRC-5 cells (human embryonic lung cells; ATCC CCL-171; propagated in-house) as the host system. Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to ATS Labs Protocol No. REK01062105.CMV (copy not provided). The product was received ready-to-use in aerosol spray cans. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were made by spreading 0.2 ml of stock virus on the bottoms of separate sterile, glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For each product lot, one dried virus film was sprayed for 3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 30 seconds at 20.0°C. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 10% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of each dilution. The subcultures were incubated at 37.0°C in a humidified atmosphere of 5.5-6.1% CO_2 and scored periodically for 24 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus titer, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The average titer of the dried virus control was **4.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the average reduction in viral titer was **≥4.0 $\log_{10}$** for both batches.

Note: The applicant provided the data for a failed trial set up on July 12, 2005. In that trial, the dried carrier count was below the required number (at least 10^4). Thus, the test was invalid. These data were not used to evaluate efficacy of the product. Testing was repeated on August 9, 2005. The repeat assay was terminated due to the presence of a viral contaminant (not the test virus). Testing was repeated on August 26, 2005. See Attachments I and II of the laboratory report.

3. MRID 469185-03 "Virucidal Effectiveness Test Using Hantavirus," for Formula 677-180, by Lisa M. Lundberg. Study conducted at MicroBioTest, Inc. Study completion date – January 20, 2006. Laboratory Project Identification Number 121-189.

This study was conducted against Hantavirus (Prospect Hill virus; obtained from Dr. B. Hjelle, University of New Mexico) using Vero E6 cells (obtained from ZeptoMetrix) as the host system. Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to a MicroBioTest Protocol "Virucidal Effectiveness Test Using Hantavirus," dated June 19, 2005 (copy provided). The product was received ready-to-use in spray cans. The stock virus culture contained at least 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile Petri dishes. The virus films were dried for 55 minutes at 21°C. For each lot of product, separate dried virus films were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface, and allowed to remain wet for 30 seconds at 21°C. After the contact period, the virus-disinfectant mixture was neutralized with fetal bovine serum. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was diluted serially in RPMI 1640 with 10% fetal bovine serum. Vero E6 cells were inoculated in

quadruplicate with an unspecified amount of selected dilutions. The cultures were incubated for 10-14 days at 35±2°C in 5±1% CO_2. Following incubation, infectivity was assayed using an indirect immunofluorescence assay. Controls included those for cell viability, plate recovery, cytotoxicity, cytotoxicity-related viral interference, and neutralizer effectiveness. The 50% fluorescent focus forming unit dose per mL ($FFFUD_{50}$/mL) was determined by the method of Reed and Muench. The average titer of the dried virus control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the average reduction in viral titer was **≥5.5 $\log_{10}$** for both batches.

Note: The following exception to compliance with GLP standards was reported – the contact time was not documented in strict compliance with 40 CFR 160.130(e).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant described a failed trial set up on August 17, 2005. During a wash step to prepare the cells for staining, the cell sheets detached from the assay plates. Testing was terminated. No results were generated.

4. MRID 469185-04 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus – Confirmatory Assay" for Formula 677-180, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – May 22, 2006. Study Identification Number A03835.

This study, under the direction of Study Director Mary J. Miller, was conducted against Feline calicivirus (F-9 strain; ATCC VR-782; a surrogate for Norovirus) using Crandel Reese feline kidney cells (CRFK cells; ATCC CCL-94; propagated in-house) as the host system. One lot (Lot No. 960-032) of the product, Formula 677-180, was tested according to ATS Labs Protocol No. REK01032406.FCAL.1 (copy not provided). The product was received ready-to-use in an aerosol spray can. The stock virus contained 5% fetal bovine serum as the organic soil load. Two glass carriers were tested for the single product lot against the target virus. Films of virus were made by spreading 0.2 mL of stock virus on the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 25% relative humidity. For the single product lot, separate dried virus films were sprayed with the product for 3 seconds at a distance of 6-8 inches from the carrier surface, and allowed to remain wet for 10 minutes at 20.0°C. After the contact period, the virus-disinfectant mixture was scraped from the surface of the dish with a cell scraper. Each sample was loaded onto pre-spun Sephadex columns using a syringe plunger. A 0.2 mL aliquot of the virus was resuspended in 2.0 mL of the product. Ten-fold serial dilutions were prepared, using Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. The cultures were incubated at 32.9-33.0°C in a humidified atmosphere of 5.9-6.2% CO_2 and scored periodically for 7 days for the presence or absence of specified cytopathic effects (i.e., small, rounding of the cells; slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The average titer of the dried virus control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the average reduction in viral titer was **≥5.5 $\log_{10}$** for the batch.

5. MRID 469185-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus" for Formula 677-180, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – May 12, 2006. Study Identification Number A03836.

This study, under the direction of Study Director Karen M. Ramm, was conducted against Feline calicivirus (F-9 strain; ATCC VR-782; a surrogate for Norovirus) using Crandel Reese feline kidney cells (CRFK cells; ATCC CCL-94; propagated in-house) as the host system. Two lots (Lot Nos. 960-028 and 960-032) of the product, Formula 677-180, were tested according to ATS Labs Protocol No. REK01032406.FCAL.2 (copy not provided). The product was received ready-to-use in aerosol spray cans. The stock virus contained 5% fetal bovine serum as the organic soil load. Two glass carriers were tested for each product lot against the target virus. Films of virus were made by spreading 0.2 mL of stock virus on the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 38% relative humidity. For each product lot, separate dried virus films were sprayed with the product for 3 seconds at a distance of 6-8 inches from the carrier surface, and allowed to remain wet for 10 minutes at 20.0°C. After the contact period, the virus-disinfectant mixture was scraped from the surface of the dish with a cell scraper. Each sample was loaded onto pre-spun Sephadex columns using a syringe plunger. A 0.2 mL aliquot of the virus was resuspended in 2.0 mL of the product. Ten-fold serial dilutions were prepared, using Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. The cultures were incubated at 32.9-33.0°C in a humidified atmosphere of 5.9-6.0% CO_2 and scored periodically for 7 days for the presence or absence of specified cytopathic effects (i.e., small, rounding of the cells; slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The average titer of the dried virus control was **6.625 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the average reduction in viral titer was **≥6.125 $\log_{10}$** for both batches.

6. MRID 469185-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Soft Surfaces," Virus: Influenza A (H1N1) virus for Formula 677-180, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – May 24, 2006. Study Identification Number A03790.

Note: This study was not reviewed, because the Agency does not accept soft surface virucidal claims.

7. MRID 469185-07 "Fungicidal Germicidal Spray Method," Test Organism: *Stachybotrys chartarum* (ATCC 66239) for Formula 677-180, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – October 20, 2005. Study Identification Number A03067.

This study was conducted against *Stachybotrys chartarum* (ATCC 66239). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10)

glass slide carriers per product lot were inoculated with 0.01 mL of a conidial suspension of the test organism. The carriers were dried for 30 minutes at 36.0°C at 40% humidity. For each lot of product, carriers were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 10 minutes at 21°C at 46% humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Trypticase Soy Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. The carriers were transferred to secondary subcultures of 20 mL of Trypticase Soy Broth at least 30 minutes after the first transfer. All subcultures were incubated for 10 days at 27.0°C. The subcultures were stored for 2-3 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Stachybotrys chartarum*** **1.6 x 10^4**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on August 4, 2005. Viability and neutralization confirmation controls both failed. Thus, the test was invalid. A different neutralizer was selected. Testing was repeated on August 31, 2005. See Attachment I of the laboratory report.

8. MRID 469185-08 "Fungicidal Germicidal Spray Method," Test Organism: *Fusarium solani* (ATCC 36031) for Formula 677-180, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – February 27, 2006. Study Identification Number A03154.

This study was conducted against *Fusarium solani* (ATCC 36031). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of a conidial suspension of the test organism. The carriers were dried for 30 minutes at 36.0°C at 40% humidity. For each lot of product, carriers were sprayed with the product for 3 seconds at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 10 minutes at 23.0°C at 25.5% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. The carriers were transferred to secondary subcultures of 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes after the first transfer. All subcultures were incubated for 10 days at 27.0°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Fusarium solani*** **1.6 x 10^4**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on September 1, 2005. Due to gross contamination of the test subcultures, the study was repeated on October 24, 2005. See Attachment I of the laboratory report.

9. MRID 469185-09 "Fungicidal Germicidal Spray Method," Test Organism: *Penicillium chrysogenum* (ATCC 9178) for Formula 677-180, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – January 10, 2006. Study Identification Number A03177.

This study was conducted against *Penicillium chrysogenum* (ATCC 9178). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of a conidial suspension of the test organism. The carriers were dried for 30 minutes at 36.0°C at 40% humidity. For each lot of product, carriers were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 10 minutes at 22.0°C at 44.3% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. The carriers were transferred to secondary subcultures of 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes after the first transfer. All subcultures were incubated for 10 days at 27.0°C. The subcultures were stored for 1 day at 5.3-5.4°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The average reported initial colony forming units per carrier, for the test microorganism, is: ***Penicillium chrysogenum* 6.65 x 10^5**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

10. MRID 469185-10 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Burkholderia cepacia* (ATCC 25416) for Formula 677-180, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – January 31, 2006. Master Schedule No. 2005-0183.

This study was conducted against *Burkholderia cepacia* (ATCC 25416). Two lots (Lot Nos. 960-030 and 960-032) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 42 minutes at 34.3-35.5°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.4°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~73 hours at 28.7-29.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count

(i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Burkholderia cepacia* 4.3 x 10^4.**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

11. MRID 469185-11 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Salmonella enterica* subspecies *enterica* serovar Enteritidis (ATCC 13076) for Formula 677-180, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – January 12, 2006. Master Schedule No. 2005-0156.

This study was conducted against *Salmonella enterica* subspecies *enterica* serovar enteritidis (ATCC 13076; commonly referred to as *Salmonella enteritidis*). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 40 minutes at 34.7-35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.0-23.4°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~48 hours at 34.3-35.5°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The average reported initial colony forming units per carrier, for the test microorganism, is: ***Salmonella enteritidis* 1.167 x 10^5.**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

12. MRID 469185-12 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Staphylococcus epidermidis* (ATCC 12228) for Formula 677-180, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – September 26, 2005. Master Schedule No. 2005-0078.

This study was conducted against *Staphylococcus epidermidis* (ATCC 12228). Three lots (Lot Nos. 960-28, 960-030, and 960-032) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 55 minutes at 33.9-34.7°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.0°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~112 hours at 33.9-37.5°C. Following incubation, the subcultures were examined

for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Staphylococcus epidermidis*** **1.2×10^6.**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: Page 27 of the laboratory report was not included, rather a duplicate of page 23 was provided. Based on information contained in similar laboratory reports provided in the data package, page 27 likely discusses the neutralization protocol.

13. MRID 469185-13 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Candida albicans* (ATCC 10231) for Formula 677-180, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 10, 2006. Master Schedule No. 2005-0151.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 72±2 hour old suspension of the test organism. The carriers were dried for 40 minutes at 34.3-34.7°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.4-23.8°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~66 hours at 29.5-29.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Candida albicans*** **1.2×10^4.**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

14. MRID 469185-14 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Salmonella enterica* subspecies *enterica* serovar Paratyphi B (ATCC 10719) for Formula 677-180, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – January 12, 2006. Master Schedule No. 2005-0154.

This study was conducted against *Salmonella enterica* subspecies *enterica* serovar Paratyphi B (ATCC 10719; commonly referred to as *Salmonella paratyphi*). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the

test organism. The carriers were dried for 40 minutes at 34.3-35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.0°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~48 hours at 34.3-35.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The average reported initial colony forming units per carrier, for the test microorganism, is: ***Salmonella paratyphi* 1.69 x 10^6.**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

15. MRID 469185-15 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Proteus mirabilis* (ATCC 25933) for Formula 677-180, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – June 2, 2006. Master Schedule No. 2005-0191.

This study was conducted against *Proteus mirabilis* (ATCC 25933). Two lots (Lot Nos. 960-030 and 960-032) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 40 minutes at 35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 22.7°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~89 hours at 32.7-35.1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Proteus mirabilis* 4.585 x 10^5.**

Note: The applicant described a failed trial set up on January 11, 2006. The laboratory failed to verify the identity of the challenge microorganism. Test results were deemed inconclusive. Testing was repeated on February 23, 2006. See pages 14 and 15 and Appendix B of the laboratory report.

Note: The discussion in the "Unforeseen Circumstance(s)" section contains inconsistent information. The discussion states that the study analyst read results on February 27, 2006 and, as a result, the assay was repeated on February 23, 2006. The date on which results were read should be prior the date on which the assay was repeated.

16. MRID 469185-16 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Acinetobacter calcoaceticus* (ATCC 15473) for Formula 677-180, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – February 3, 2006. Master Schedule No. 2005-0172.

This study was conducted against *Acinetobacter calcoaceticus* (ATCC 15473). Two lots (Lot Nos. 960-030 and 960-032) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 40 minutes at 35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 22.7°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~48 hours at 34.3-35.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Acinetobacter calcoaceticus* 8.75 x 10^5**.

17. MRID 469185-17 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Pseudomonas putida* (ATCC 12633) for Formula 677-180, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – March 24, 2006. Master Schedule No. 2005-0182.

This study was conducted against *Pseudomonas putida* (ATCC 12633). Two lots (Lot Nos. 960-030 and 960-032) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 41 minutes at 34.3-35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.4°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~48 hours at 29.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Pseudomonas putida* 1.55 x 10^5**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on November 9, 2005. In that trial, the dried carrier count was below the required number (at least 10^4). Thus, the test was invalid. These data were not used to evaluate efficacy of the product. Testing was repeated on December 7, 2005. See page 14 and Appendix B of the laboratory report.

18. MRID 469185-18 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Serratia marcescens* (ATCC 14756)

for Formula 677-180, by Kyle T. Smith. Study conducted at Reckitt Benckiser Inc. Study completion date – February 13, 2006. Master Schedule No. 2005-0159.

This study was conducted against *Serratia marcescens* (ATCC 14756). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 41 minutes at 34.3-35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.4°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~48 hours at 29.5-29.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Serratia marcescens* 4.55 x 10^5**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

19. MRID 469185-19 "Additional Microorganism Disinfectant Efficacy Testing In The Presence of Organic Soil," Test Organism: *Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539) for Formula 677-180, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – March 7, 2006. Master Schedule No. 2005-0155.

This study was conducted against *Salmonella enterica* subspecies *enterica* serovar typhi (ATCC 6539; commonly referred to as *Salmonella typhi*). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 mL of a 48±2 hour old suspension of the test organism. The carriers were dried for 41 minutes at 35.1°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 10 minutes at 23.4°C. After exposure, individual carriers were transferred to 20 mL of Letheen Broth to neutralize. All subcultures were incubated for ~49 hours at 34.3-35.5°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, organism survivor count (i.e., dried carrier count), test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Salmonella typhi* 2.3 x 10^4**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

20. MRID 469185-20 "AOAC Germicidal Spray Method," Test Organism: *Neisseria elongata* (ATCC 25295) for Formula 677-180, by Anne Stemper. Study conducted

at ATS Labs. Study completion date – March 7, 2006. Study Identification Number A03475.

This study was conducted against *Neisseria elongata* (ATCC 25295). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method (modified) as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of a ~48 hour old suspension of the test organism. The carriers were dried for 30 minutes at 36.0°C at 40% relative humidity. Each carrier was sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 10 minutes at 20°C at 14% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Fluid Thioglycollate Medium with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for ~47 hours at 36.0°C in 6.0% CO_2. The subcultures were stored for 1 day at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Because none of the subculture tubes were turbid, each subculture tube (e.g., test, neutralization control, viability control) was subcultured to chocolate agar and incubated for ~45 hours at 36.0°C and 6.0% CO_2. The plates were then examined to determine the presence or absence of growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average initial colony forming units per carrier, for the test microorganism, is: ***Neisseria elongata* 6.5 x 10^4**.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

21. MRID 469185-21 "AOAC Germicidal Spray Method," Test Organisms: *Corynebacterium diptheriae* (ATCC 11913), *Streptococcus salivarius* (ATCC 7073), and *Proteus vulgaris* (ATCC 9920) for Formula 677-180, by Anne Stemper. Study conducted at ATS Labs. Study completion date – March 7, 2006. Study Identification Number A03474.

This study was conducted against *Corynebacterium diptheriae* (ATCC 11913), *Streptococcus salivarius* (ATCC 7073), and *Proteus vulgaris* (ATCC 9920). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested according to the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use in aerosol spray cans. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 mL of a ~47 hour old suspension of the test organism. The carriers were dried for 30 minutes at 36.0°C at 40% relative humidity. Each carrier was sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface. Each carrier remained exposed to the product for 10 minutes at 20°C at 14% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for ~46 hours at 36.0°C. The subcultures were stored for 1 day at 2-8□C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. The reported average initial colony forming

units per carrier, for the test microorganisms, are: ***Corynebacterium diptheriae*** **1.75 x 10^5, *Streptococcus salivarius* 3.8 x 10^4, and *Proteus vulgaris* 3.5 x 10^4.**

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

22. MRID 469185-22 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Surface Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organism: *Aspergillus niger* (ATCC 16404) for Formula 677-180, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – October 18, 2005. Study Identification Number A03069.

Note: This study was not reviewed, because the Agency does not accept soft surface sanitizer claims.

23. MRID 469185-23 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Surface Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352) for Formula 677-180, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – November 7, 2005. Study Identification Number A03070.

Note: This study was not reviewed, because the Agency does not accept soft surface sanitizer claims.

24. MRID 469185-24 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Surface Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organism: *Aspergillus niger* (ATCC 16404) for Formula 677-180, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – November 29, 2005. Study Identification Number A03228.

Note: This study was not reviewed, because the Agency does not accept soft surface sanitizer claims.

25. MRID 469185-25 "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Surface Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organism: *Proteus mirabilis* (ATCC 9240) for Formula 677-180, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – December 13, 2005. Study Identification Number A03068.

Note: This study was not reviewed, because the Agency does not accept soft surface sanitizer claims.

26. MRID 469185-26 "Sanitization Study: Quantitative Reduction of Fungi on Non-Food Contact Surface," Test Organism: *Trichophyton mentagrophytes* (ATCC 9533) for Formula 677-180, by Kelly Whitehead. Study conducted at Reckitt Benckiser Inc. Study completion date – June 2, 2006. Amended report date – July 7, 2006. Master Schedule No. 2005-0188.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 960-028 and 960-032) of the product, Formula 677-180, were tested using ASTM Standard Method E1153-87, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces. The product was received ready-to-use in aerosol spray cans. Horse serum was added to the culture to achieve a 5% organic soil load. Five sterile glass slide carriers per product lot were inoculated with 0.02 mL of a suspension of the test organism. The carriers were dried for 41 minutes at 33.1-33.9°C. Each carrier was sprayed for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers were allowed to remain wet for 30-31 seconds at 22.3-22.7°C. After exposure, individual carriers were transferred to 10 mL of Letheen Broth to neutralize. Additional carriers were treated with a non-active control substance (i.e., 0.01% Triton X-100). All subcultures were incubated for 7 days at 29.8°C. Following incubation, the subcultures were examined for the presence or absence of visible growth, and colonies were counted. Controls included those for inoculum count, dried recovery control count, test system verification (i.e., purity and identity of the challenge microorganism), neutralizer efficacy, and sterility.

Note: The following exception to GLP standards was reported – the stability, uniformity, and solubility of the non-active control substance were unknown at the time of testing.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for a failed trial set up on December 14, 2005. In that trial, the product was tested at a 10-minute contact time. In addition, neutralization was not demonstrated using D/E Broth as the neutralizer. Thus, the test was invalid. These data were not used to evaluate efficacy of the product. Testing was repeated on January 4, 2006. See page 16 and Appendix C of the laboratory report.

27. MRID 469185-27 "Inactivation of Rotavirus in the Presence of Organic Matter" for Formula 677-180, by Christine Dellanno. Study conducted at Reckitt Benckiser Inc. Study completion date – July 13, 2006. Master Schedule No. 2005-0184.

This study was conducted against Rotavirus (Strain WA; ATCC VR-2018), using MA-104 (obtained from Diagnostic Hybrids) as the host system. Two lots (Lot Nos. 960-028 and 960-032) of the product, Formula 677-180, were tested according to a Reckitt Benckiser Inc. Protocol titled "Inactivation of Rotavirus in the Presence of Organic Matter" (copy provided). The product was received ready-to-use in aerosol spray cans. [Although referenced in the report title, the laboratory report did not indicate whether the stock virus culture was adjusted to contain an organic soil load.] Two carriers were tested for each product lot against the target virus. Films of virus were prepared by spreading 0.3 mL of virus inoculum uniformly over the bottoms of separate sterile polystyrene Petri dishes. The virus films were dried for 33-41 minutes at 24.0-24.7°C. For each lot of product, separate dried virus films were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 30 seconds at 24.0-24.7°C. Approximately 25 seconds prior to the end of the 30-second contact time, the plates were scraped with a cell scraper to re-suspend the contents. [If the re-suspended volume was less than 2.0 mL, the volume was adjusted to 2.0 mL with the addition of maintenance media (i.e., Minimum Essential Medium supplemented with gentamicin and 5 µg/mL trypsin).] At the designated contact time of 30 seconds, the virus-disinfectant mixture was neutralized by transferring 0.2 mL of the virus-disinfectant mixture into 1.8 mL of maintenance medium. Ten-fold serial dilutions were

prepared, using maintenance medium. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of each dilution. The cultures were incubated at 35.8-36.6°C in 5% CO_2 and scored periodically for 5 days for the presence or absence of cytopathic effects (i.e., degeneration of cell sheet) and toxicity. Controls included those for host cell viability, dried virus counts, and toxicity. ID_{50} titers were determined by the method of Reed and Muench.

Note: The following exception to GLP standards was reported – the equipment number of the balance used to prepare reagents was not recorded.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

28. MRID 469185-28 "Inactivation of Influenza A Virus (H1N1) in the Presence of Organic Matter" for Formula 677-180, by Christine Dellanno. Study conducted at Reckitt Benckiser Inc. Study completion date – July 13, 2006. Master Schedule No. 2006-0042.

This study was conducted against Influenza A (H1N1) virus (Strain A/Malaya/302/54; ATCC VR-98), using embryonated chicken eggs (obtained from Abma's Farm Wholesale Produce) as the host system. Two lots (Lot Nos. 960-030 and 960-032) of the product, Formula 677-180, were tested according to a Reckitt Benckiser Inc. Protocol titled "Inactivation of Influenza A Virus (H1N1) in the Presence of Organic Matter" (copy provided). The product was received ready-to-use in aerosol spray cans. [Although referenced in the report title, the laboratory report did not indicate whether the stock virus culture was adjusted to contain an organic soil load.] Two carriers were tested for each product lot against the target virus. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile polystyrene Petri dishes. The virus films were dried for 26-31 minutes at 24.4-25.5°C. For each lot of product, separate dried virus films were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface. The carriers remained exposed to the product for 30 seconds at 24.4-25.5°C. After at least 5 seconds, the plates were scraped with a cell scraper to re-suspend the contents. [If the re-suspended volume was less than 2.0 mL, the volume was adjusted to 2.0 mL with the addition of maintenance media (i.e., Minimum Essential Medium supplemented with gentamicin).] At the designated contact time of 30 seconds, the virus-disinfectant mixture was neutralized by transferring 0.2 mL of the virus-disinfectant mixture into 1.8 mL of maintenance medium. Ten-fold serial dilutions were prepared, using maintenance medium. Embryonated eggs were inoculated intra-allantoically in quadruplicate with 0.2 mL of each dilution. The eggs were candled prior to use to determine viability and fertility. The eggs were incubated for 3 days at 33.7-34.1°C. Following incubation, the eggs were chilled at -16.6-9.5°C. A 0.5 mL aliquot of the allantoic fluid was harvested. The samples were assayed for the presence of replicating virus using an hemagglutination assay. Controls included those for host cell viability, dried virus counts, and toxicity. ID_{50} titers were determined by the method of Reed and Muench.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

29. MRID 469185-29 "EPA Hard Surface Mildew-Fungistatic Test," Test Organism: *Alternaria alternata* (ATCC 13963) for Formula 677-180, by Sally Nada. Study conducted at ATS Labs. Study completion date – November 17, 2005. Study Identification Number A03221.

This study was conducted against *Alternaria alternata* (ATCC 13963). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the Hard Surface Mildew Fungistatic Test Method. The product was received ready-to-use in aerosol spray cans. A 0.1 mL aliquot of the conidial suspension was added to 20 mL of sterile Czapek's solution. Fetal bovine serum was added to the conidial/Czapek suspension to achieve a 5% organic soil load. For each lot of the product, ten (10) glazed ceramic tiles were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface, and allowed to remain wet for 3 minutes. After treatment, the tiles were dried for 105 minutes at 36.0°C at 26.3% relative humidity. Following the drying period, the surfaces of each test tile and each untreated control tile were sprayed with the conidial/Czapek suspension containing 5% fetal bovine serum using a DeVilbiss #151 Atomizer. The tiles were dried for 153 minutes at 36.0°C at 22.3% relative humidity. After drying, each tile was placed in an individual Petri dish containing hardened sterile water agar. The plates were incubated for 7 days at 27.0°C at 97.1% relative humidity. The tiles were examined for the presence or absence of fungal growth after 7 days of incubation. When no growth was visually observed, a magnified examination was performed. Controls included those for purity and sterility.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

30. MRID 469185-30 "EPA Hard Surface Mildew-Fungistatic Test," Test Organism: *Penicillium chrysogenum* (ATCC 9178) for Formula 677-180, by Sally Nada. Study conducted at ATS Labs. Study completion date – October 25, 2005. Study Identification Number A03190.

This study was conducted against *Penicillium chrysogenum* (ATCC 9178). Two lots (Lot Nos. 960-028 and 960-030) of the product, Formula 677-180, were tested using the Hard Surface Mildew Fungistatic Test Method. The product was received ready-to-use in aerosol spray cans. A 0.1 mL aliquot of an adjusted conidial suspension was added to 20 mL of sterile Czapek's solution. Fetal bovine serum was added to the conidial/Czapek suspension to achieve a 5% organic soil load. For each lot of the product, ten (10) glazed ceramic tiles were sprayed with the product for 2-3 seconds at a distance of 6-8 inches from the carrier surface, and allowed to remain wet for 3 minutes at 21.0°C at 50.8% humidity. After treatment, excess liquid was allowed to drain. The tiles were dried for 108 minutes at 36.0°C at 27.5% relative humidity. Following the drying period, the surfaces of each test tile and each untreated control tile were sprayed with the conidial/Czapek suspension containing 5% fetal bovine serum using a DeVilbiss #151 Atomizer. The tiles were dried for 4 hours at 36.0°C at 25.1% relative humidity. After drying, each tile was placed in an individual Petri dish containing hardened sterile water agar. The plates were incubated for 7 days at 27.0°C at 95.4% relative humidity. The tiles were examined for the presence or absence of fungal growth after 7 days of incubation. When no growth was visually observed, a magnified examination was performed. Controls included those for purity and sterility.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested			Carrier Population (CFU/carrier)
		Lot No. 960-028	Lot No. 960-030	Lot No. 960-032	
469185-07	*Stachybotrys chartarum*	1°=0/10 2°=0/10	1°=0/10 2°=0/10		1.6×10^4
469185-08	*Fusarium solani*	1°=0/10 2°=0/10	1°=0/10 2°=0/10		1.6×10^4
469185-09	*Penicillium chrysogenum*	1°=0/10 2°=0/10	1°=0/10 2°=0/10		5.3×10^5 and 8.0×10^5
469185-10	*Burkholderia cepacia*		0/10	0/10	5.2×10^4 and 3.4×10^4
469185-11	*Salmonella enteritidis*	0/10	0/10		1.44×10^4 and 2.19×10^5
469185-12	*Staphylococcus epidermidis*	0/10	0/10	0/10	1.12×10^6 and 1.28×10^6
469185-13	*Candida albicans*	0/10	0/10		1.0×10^4 and 1.4×10^4
469185-14	*Salmonella paratyphi*	0/10	0/10		1.11×10^6 and 2.27×10^6
469185-15	*Proteus mirabilis*		0/10	0/10	7.0×10^5 and 2.17×10^5
469185-16	*Acinetobacter calcoaceticus*		0/10	0/10	7.6×10^6 and 9.9×10^6
469185-17	*Pseudomonas putida*		0/10	0/10	1.68×10^5 and 1.42×10^5
469185-18	*Serratia marcescens*	0/10	0/10		4.7×10^5 and 4.4×10^5
469185-19	*Salmonella typhi*	0/10	0/10		3.0×10^4 and 1.6×10^4
469185-20	*Neisseria elongata*	0/10	0/10		6.5×10^4
469185-21	*Corynebacterium diptheriae*	0/10	0/10		1.75×10^5
	Streptococcus salivarius	0/10	0/10		3.8×10^4
	Proteus vulgaris	0/10	0/10		3.5×10^4

MRID Number	Organism	Results			Dried Virus Control
			Lot No. 960-028	Lot No. 960-030	
469185-01	Vaccinia virus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{7.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
469185-02	Cytomegalovirus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

MRID Number	Organism	Results			Dried Virus Control
469185-03	Hantavirus	10^{-2} dilution	Cytotoxicity	Cytotoxicity	$10^{6.00}$ $FFFUD_{50}$/ mL
		10^{-3} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$FFFUD_{50}$/mL	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		Log reduction	≥ 3.5 $\log_{10}$	≥ 3.5 $\log_{10}$	
			Lot No. 960-028	**Lot No. 960-032**	
469185-04	Feline calicivirus	10^{-1} to 10^{-4} dilutions		Complete inactivation	$10^{6.25}$ and $10^{5.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL		$\leq 10^{0.5}$	
469185-05	Feline calicivirus	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{6.5}$ and $10^{6.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
469185-27	Rotavirus	10^{-2} dilution	Cytotoxicity (one replicate)	Cytotoxicity	$10^{6.00}$ ID_{50}
		10^{-3} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	
		ID_{50}	$\leq 10^{1.50}$ and $\leq 10^{2.50}$	$\leq 10^{2.50}$ and $\leq 10^{2.33}$	
		Log reduction	≥ 3.5 $\log_{10}$	≥ 3.5 $\log_{10}$	
			Lot No. 960-030	**Lot No. 960-032**	
469185-28	Influenza A (H1N1) virus	10^{-2} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.50}$ ID_{50}
		ID_{50}	$\leq 10^{1.50}$	$\leq 10^{1.50}$	

MRID Number	Organism	Lot No.	Average No. Surviving (CFU/carrier)	Microbes Initially Present (CFU/carrier)	Percent Reduction
469185-26	*Trichophyton mentagrophytes*	960-028	$<1.22 \times 10^0$	4.79×10^4	>99.9
		960-032	2.00×10^0	4.79×10^4	99.9

MRID Number	Organism	% Growth		
		Lot No. 960-028	Lot No. 960-030	Control Tiles
469185-29	*Alternaria alternata*	0/10	0/10	10/10*
469185-30	*Penicillium hrysogenum*	0/10	0/10	10/10*

* At least 50% fungal growth on each untreated control tile was observed.

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, Brace, as a disinfectant on hard, non-porous surfaces against the following microorganisms in the presence of a 5% organic soil load for a contact time of 10 minutes:

Acinetobacter calcoaceticus MRID No. 469185-16

Burkholderia cepacia	MRID No. 469185-10
Corynebacterium diptheriae	MRID No. 469185-21
Neisseria elongata	MRID No. 469185-20
Proteus mirabilis	MRID No. 469185-15
Proteus vulgaris	MRID No. 469185-21
Pseudomonas putida	MRID No. 469185-17
Salmonella enteritidis	MRID No. 469185-11
Salmonella paratyphi	MRID No. 469185-14
Salmonella typhi	MRID No. 469185-19
Serratia marcescens	MRID No. 469185-18
Staphylococcus epidermidis	MRID No. 469185-12
Streptococcus salivarius	MRID No. 469185-21
Candida albicans	MRID No. 469185-13
Fusarium solani	MRID No. 469185-08
Penicillium chrysogenum	MRID No. 469185-09

Complete killing was observed in the subcultures of all carriers tested against the required number of product lots. Carrier population (e.g., organism survivor) counts were at least 10^4 CFU/carrier. Organism survivor counts were at least 10^4 for *Candida albicans*, which is consistent with EPA's interim policy. [For more details about this interim policy, see Section III of this efficacy report.] Neutralizer testing/ neutralization confirmation testing showed positive growth of the microorganisms. When reported, viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID No. 469185-07) **do not support** the use of the product, Brace, as a disinfectant with fungicidal activity against *Stachybotrys chartarum* on hard, non-porous surfaces for a contact time of 10 minutes. **The Agency has not yet accepted this protocol for use in determining efficacy of product against *Stachybotrys chartarum*.**

3. The submitted efficacy data **support** the use of the product, Brace, as a disinfectant with virucidal activity on hard, non-porous surfaces against the following microorganisms in the presence of at least a 5% organic soil load for the contact time listed:

Cytomegalovirus	30 seconds	MRID No. 469185-02
Feline calicivirus	10 minutes	MRID Nos. 469185-04 and -05
Hantavirus	30 seconds	MRID No. 469185-03
Vaccinia virus	30 seconds	MRID No. 469185-01

Recoverable virus titers of at least 10^4 were achieved. In studies against Hantavirus, cytotoxicity was observed in the 10^{-2} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. In studies against all other viruses, complete inactivation (no growth) was observed in all dilutions tested. Initial and confirmatory studies against Feline calicivirus were performed at the same laboratory but under different study directors. Confirmatory studies used one lot of product, not the standard two.

4. The submitted efficacy data (MRID Nos. 469185-27 and -28) **do not currently support** the use of the product, Brace, as a disinfectant with virucidal activity on hard, non-porous surfaces against **Rotavirus** and **Influenza A (H1N1) virus** for a contact time of 30 seconds. **Efficacy**

against **Rotavirus** and **Influenza A (H1N1) virus** for a contact time of 30 seconds. **Efficacy studies did not include a neutralization confirmation control to demonstrate the selected neutralizer's ability to inactivate the product.**

5. The submitted efficacy data (MRID No. 469185-26) **do not support** the use of the product, Brace, as a sanitizer against *Trichophyton mentagrophytes* on hard, non-porous, non-food contact surfaces. **The Agency does not accept sanitizing claims for fungi.**

6. The submitted efficacy data (MRID Nos. 469185-29 and 469185-30) **support** the use of the product, Brace, as a fungistat against *Alternaria alternata* and *Penicillium chrysogenum* on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 3 minutes. No growth was observed 7 days after treatment. Testing was conducted on 2 product lots. Untreated control tiles exhibited growth of the challenge microorganisms on at least 50% of the untreated tile surface. Purity controls were reported as pure. Sterility controls did not show growth.

7. The submitted efficacy data **do not support** the use of the product, Brace, on **soft surfaces** against the following microorganisms:

Influenza A (H1N1) virus	MRID No. 469185-06
Aspergillus niger	MRID Nos. 469185-22 and -24
Klebsiella pneumoniae	MRID No. 469185-23
Proteus mirabilis	MRID No. 469185-25
Staphylococcus aureus	MRID No. 469185-23

The Agency does not accept soft surface claims for disinfectants and sanitizers.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Brace, is an effective disinfectant on hard, non-porous surfaces against the following microorganisms for a contact time of 10 minutes:

Acinetobacter calcoaceticus
Burkholderia cepacia
Corynebacterium diptheriae
Neisseria elongata
Proteus mirabilis
Proteus vulgaris
Pseudomonas putida
Salmonella enteritidis
Salmonella paratyphi
Salmonella typhi
Serratia marcescens
Staphylococcus epidermidis
Streptococcus salivarius
Candida albicans
Fusarium solani
Penicillium chrysogenum
Feline calicivirus

Data provided by the applicant **support** these claims.

2. The proposed label claims that the product, Brace, is an effective disinfectant on hard, non-porous surfaces against Cytomegalovirus, Hantavirus, and Vaccinia virus for a contact time of 30 seconds. Data provided by the applicant **support** these claims. The following information must be included on the label because of Hantavirus claims:

"Rodent droppings and visible dust may be reservoirs for Hantavirus. If you are cleaning out a building that has been closed up, such as a cabin, shed, or garage:

- **Air out the building for at least 30 minutes by opening windows and doors.**
- **Leave the building while it is airing out.**
- **Do not vacuum, sweep or dust. This may spread the virus through the air.**
- **Thoroughly wet the contaminated areas with the product and allow to stand undisturbed for contact time specified by the manufacturer's label.**
- **Carefully remove contaminated material and dispose by burial or burning. Contact your local or state health department for additional disposal methods.**
- **Treat the surface again following the manufacturer's label directions."**

3. The proposed label claims that the product, Brace, is an effective disinfectant on hard, non-porous surfaces against Influenza A (H1N1) virus and Rotavirus for a contact time of 30 seconds. Data provided by the applicant **do not support** these claims. As discussed in the "Conclusions" section of this report, testing did not include a neutralization confirmation control. **All references to Influenza A (H1N1) virus and Rotavirus must be removed from the product label. Additionally remove the verbiage for Farm Premise, Livestock, Poultry & Turkey Disinfection, as these directions support Avian Influenza claims.**

4. The proposed label claims that the product, Brace, is an effective disinfectant on hard, non-porous surfaces against *Stachybotrys chartarum* for a contact time of 10 minutes. Data provided by the applicant **do not support** these claims. As discussed in the "Conclusions" section of this report, applicants must receive the Agency approval of a testing protocol prior to its use. **All references to *Stachybotrys chartarum* must be removed from the product label.**

5. The proposed label claims that the product, Brace, is an effective fungistat on hard, non-porous surfaces against *Alternaria alternate* and *Penicillium chrysogenum.* Data provided by the applicant **support** these claims.

6. The proposed label claims that the product, Brace, is an effective sanitizer on hard, non-porous surfaces against *Trichophyton mentagrophytes* for a contact time of 30 seconds. Data provided by the applicant **do not support** this claim. As discussed in the "Conclusions" section of this report, the Agency does not accept sanitizing claims for fungi. **The "30-sec Sanitization against Fungi" section must be removed from page 8 of the proposed label.**

7. The proposed label claims that the product, Brace, is an effective disinfectant and sanitizer on soft surfaces. The Agency does not accept soft surface claims for disinfectants and sanitizers. **References to soft surface claims on pages 4, 6, 8, and 9 of the proposed label must be removed.**

8. The "30 Second Disinfection Claim" section of page 5 of the proposed label includes a claim that the product kills 99.9% of germs; however, **the 99.9% claim is typically appropriate for sanitizing claims, not disinfectant claims. Similarly, remove the marketing claim "Your family comes in contact with germs everyday (both in the home and in public places...this product kill 99.9% of viruses and bacteria on commonly touched environmental surfaces..." to the area designated for sanitization claims.**

9. The new disinfecting claims "Kills (viruses) (bacteria) in seconds" on page 5 of the proposed label needs to be qualified. **The majority of microorganisms require a 10 minute contact time.**

10. Revise the proposed to include Hepatitis B in the Special Instructions section for bloodborne pathogens.

11. The applicant must make the following changes to improve the proposed label:

- On page 5 of the proposed label, **delete the disinfecting claim "Universal blood born pathogen decontaminant."**
- On page 5 of the proposed label, change "**nook and crannies**" to read "**nooks and crannies**."
- On page 7 of the proposed label, change "**Hepatatis B**" to read "**Hepatitis B virus**."
- On page 7 of the proposed label, change "**10 mintues**" to read **10 minutes**."
- On page 7 of the proposed label under the "Farm Premise . . ." section, change "**coups**" to read "**coops**" and "**feed tracks**" to read "**feed racks**."
- On page 7 of the proposed label under the "Veterinary Practice . . ." section, change "**rinse with portable water**" to read "**rinse with potable water**."
- On page 8 of the proposed label, change "***Alternaria alternate***" to read "***Alternaria alternata***."
- On page 9, delete "**ceramic tile**," as this is a porous surface.